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10/768,760	01/29/2004	Tom Minh Miner	5434-16	7041

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EXAMINER	
OSINSKI, BRADLEY JAMES	

ART UNIT	PAPER NUMBER
3767	

NOTIFICATION DATE	DELIVERY MODE
07/09/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/768,760	MINH MINER ET AL.	
	Examiner	Art Unit	
	BRADLEY J. OSINSKI	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4-11-2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1-21 and 23-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ford (5,779,674) in view of Alchas (4,952,210), Knighton (4,571,244), and Bormann et al (6,336,916).

a. Regarding claim 1, In figure 1 of Ford, the coupling assembly consists of tube 14, clamp 18, and a connector for securing tube 14 to bag 12. Tube 14 has an input an output where the input is configured for coupling to container 12. Ford teaches, *"The flow of liquid from media bag through the inlet line 14 can be selectively blocked by the use of a tubing clamp 18." (Col.3 lines 59-60)*. Ford teaches, *"Drip chamber 10 comprises an elongated, tubular housing 22 and an end cap 24. Together, housing 22 and end cap 24 define an interior chamber 26 for receiving and collecting fluids. Drip chamber 10 further comprises and elongated, cylindrically shaped hydrophobic filter assembly 28 and a check valve 30." (Col.4 lines 7-12)* and *"...hydrophobic barrier that will allow air to pass from interior chamber 26, without passing fluid." (Col.4 lines 55-57)* From figure 1 it is apparent that the fluid for the system comes form bag 12 and flows in via tube 14. Ford teaches, *"Similarly, the flow of fluid of out drip chamber 10 and through*

outlet line 16 can be selectively controlled through the use of tubing clamp 20." (Col.3 lines 61-63). Ford does not teach having a side opening between the top and bottom walls. Alchas is drawn to a 'parenteral fluid administration set' (Title), the same as Ford (see abstract), and teaches a hydrophobic membrane on the side wall of a container to allow air to escape from the container. Alchas teaches, *"Venting means is provided for communicating between chambers 52 and the exterior of the housing for allowing air to enter the chamber as fluid leaves the chamber through the passageway. In this embodiment, the venting means includes an aperture 58 in the side wall of housing 51 extending between chamber 52 and the outside of the housing. Aperture 58 is covered by an air-permeable liquid-impermeable element 59 positioned so that all gases exchanged through aperture 58 pass through element 59. (Col.6 lines 65-68 and Col.7 lines 1-3).* Further it would have been obvious that placing the vent of Ford on the side of the drip chamber would function just as effectively as placing it on the top as the greater pressure inside of the drip chamber would push air out of the chamber to the atmosphere, additionally it would save on material as a long filter assembly as in figure 3 of Ford would not be needed – the vent could be a flat circular vent piece entirely incorporated into the wall of the device such as the vent of Bormann et al. Ford does not specifically teach the patient conduit terminating in an intravenous needle. Although the end of outlet line 16 is not shown, it is inherent to the device of Ford to use an intravenous needle to interface with the patient. In any event it would have been obvious to one of

ordinary skill in the art to attach an intravenous needle to the end of the outlet line 16 in order to 'administer parenteral fluids' (Ford, Abstract) to a patient. Ford only teaches a clamp 20, it does not teach expelling air in the patient conduit from the termination end. Knighton is drawn to a system for removing gas bubble from liquids, which Ford teaches as important: *"Prior to infusion of any fluid, however, it is generally desired to remove air or other gases which might be present in the solution. In many situations, removal of gas is absolutely essential to avoid a gas embolism" (Col.1 lines 13-17, Ford).* Knighton specifically states, *"The system is inexpensive and simple to use. A nurse or doctor merely inserts the device into the IV line. Entrapped gas flows out of the chamber through the second gas-passing filter, the gas-free fluid flows through the first fluid-passing filter into the patient." (Col.1 lines 66-68 to Col.2 lines 1-2)* Therefore it would have been obvious to one of ordinary skill in the art to add the gas expelling device of Knighton to the end of the patient conduit in order to further expel gas in order to avoid a gas embolism in the patient. Knighton further teaches, *"...liquid flow can be immediately resumed by returning the selector valve to its liquid flowing second position." (Col.3 lines 11-13)* Thus the flow of air and liquid in the patient conduit can be restricted until the reservoir attains the appropriate level. Ford does not teach wetting of the vent plug preventing entry of air. Bormann et al, which is drawn to a device for administration of parenteral fluids – especially a drip chamber, teaches, *"...the vent comprising a liquid sealable porous medium that allows gas in the housing to pass through the medium until*

the medium is contacted by the liquid, the vent and the housing being cooperatively arranged to allow the gas to be vented from the housing and for liquid to fill the housing to a predetermined level that is less than the total liquid capacity of the housing." (Col.2 lines 61-67). Therefore it would have been obvious to one of ordinary skill in the art to use the vent plug material of Bormann et al with Ford in order to allow the housing to be filled to a predetermined level and prevent air from entering the system when that predetermined level is reached which wets the vent plug.

b. Regarding claim 2, See 1.a above for combination of the device of Knighton with Ford. It is apparent that the device of Knighton can serve as an end cap.

c. Regarding claim 3, See 1.a above for combination of the device of Knighton with Ford. Knighton further teaches, *"The first filter is hydrophilic; it will not allow gas bubbles to pass through, but will allow liquid to pass through. The second filter is hydrophobic and allows air to pass out from the chamber but will not pass liquid. The gas-free liquid passes through the hydrophilic filter and flows into the patient." (Col.1 lines 60-65)*

d. Regarding claim 4, See 1.a and 1.b above

e. Regarding claim 5, See 1.a above for combination of device of Knighton with Ford. Knighton further teaches, *"...liquid flow can be immediately resumed by returning the selector valve to its liquid flowing second position." (Col.3 lines 11-13)* Thus the patient can be isolated from the drip chamber.

f. Regarding claim 6, It is notoriously well known to use flexible conduits of varying sizes to connect parts of IV setup. It is further well known in the art to use lengths of tubing such that as little disturbance as possible is caused to other parts of the IV setup if one part of the setup needs to be manipulated. Finally, Ford teaches, *"...a healthcare professional can estimate the flow rate of the fluid by watching the drip rate as the fluid falls through the air space in the top of the drip chamber." (Col.2 lines 33-37).* It would have been obvious tone of ordinary skill in the art to position the drip chamber close the patient so that a healthcare professional could estimate the fluid flow rate and check on the patient at the same time, with minimal movement.

g. Regarding claim 7, Ford teaches, *"Optionally, inlet line 14 may also terminate in a nozzle (not shown) that is designed to from the fluid delivered through inlet line 14 into droplet before falling into interior chamber 26." (Col.4 lines 49-52)*

h. Regarding claim 8, Ford does not teach that 1/3 of the volume of the drip chamber is occupied by the reservoir. However, Ford discloses *"The precise dimensions of housing 22 depend on the desired volume, the presently preferred ranged for which is 5-35 milliliters, as well as the desired medical application for which the drip chamber 10 is to be utilized." (Col.4 lines 21-25).* Ford does not disclose expressly the reservoir occupying 1/3 of the total volume of the drip chamber. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to place the

sidewall aperture of Ford and Alchas combined as in 1.a above at a location such that the reservoir occupies 1/3 of the volume of the drip chamber because Applicant has not disclosed that utilizing only 1/3 of the volume of the drip chamber provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with a drip chamber volume range of 5-35 mL. Therefore, it would have been an obvious matter of design choice to modify Ford to obtain the invention as specified in claim 8.

i. Regarding claim 9, See 1.a above for combination with vent plug material of Bormann et al with Ford. Bormann et al further characterizes the absorbing material via, *"A variety of materials may be used, provided the requisite properties of the porous medium 10 are achieved. These properties include the necessary strength to handle the differential pressures encountered in use and the ability to provide the desired permeability without the application of excessive pressure. Suitable starting materials include synthetic polymers including polyamides, polyesters, polyolefins, particularly polypropylene and polymethylpentene, perfluorinated polyolefins, such as polytetrafluoroethylene, polysulfones, polyvinylidene difluoride, polyacrylonitrile and the like, and compatible mixtures of polymers. Within the class of polyamides, suitable polymers include, for example, polyhexamethylene adipamide, poly-.epsilon.-caprolactam, polymethylene sebacamide, poly-7-aminoheptanoamide, polytetramethylene adipamide (nylon 46), polyhexamethylene azeleamide, and*

polyhexamethylene adipamide (nylon 66). (Col.7 lines 6-24, emphasis added) Many of these chemicals are the same as those Applicant refers to as suitable absorptive materials in paragraph 30.

j. Regarding claim 10, It would have been obvious to one of ordinary skill in the art to give the vent plug anti-bacterial properties, as it would be art recognized as a location that bacteria could enter the IV system (even with a pour size of 5 micrometers as Bormann et al teaches) and then be introduced directly into the bloodstream of the patient, and using an anti-bacterial is notoriously well known to prevent this.

k. Regarding claim 11, Looking at figure 5 of Alchas, it is apparent that if the membrane were located on the side wall of the drip chamber, the cavity/aperture would have one end in communication with the drip chamber and another in communication with the atmosphere. See 1.h regarding the super-absorbing material. Bormann et al further characterizes the vent plug via, *"In accordance with one embodiment according to FIGS. 1-3, the porous medium 10 comprises the liquophobic element and the liquophilic element arranged in the housing 14 to vent gas through gas passageway 5 until the liquophilic element is contacted or covered by the liquid being transferred." (Col.6 lines 42-48)* In this case, in order for the liquophilic element to be contacted by liquid, the liquophobic would be exposed to the atmosphere, and may be considered a venting membrane. It would have been obvious to of ordinary skill in the art to place a venting liquophobic membrane between the super-absorbent polymer and atmosphere

so that fluid and other contaminants could not enter the drip chamber from the atmosphere. Bormann et al also teaches, *"The device can include additional layers or elements, e.g. as spacers and/or supports with respect to the porous medium 10. An exemplary support or spacer layer can be a mesh or screen." (Col.7 lines 37-40)* It therefore would have been obvious to one of ordinary skill in the art to add a mesh/screen layer between the absorbing polymer and drip chamber to provide support to the absorbing polymer.

l. Regarding claim 12, See 1.i above.

m. Regarding claim 13, See 1.j above. According to the American Heritage Dictionary, a cannula is defined as 'a flexible tube, usually containing a trocar at one end, that is inserted into a bodily cavity, duct, or vessel to drain fluid or administer a substance such as a medication'. Ford does not specifically teach a cannula for securement within the side wall opening. Ford does, however, teach, *"Support structure 53 provides structural support to membrane 52, thereby preventing membrane 52 from collapsing under the force of fluid and/or gas pressures generated within the interior chamber 26. Support structure 53 can be made rigid or semi-rigid nylon, ABS, polycarbonate or other suitable material." (Col.5 lines 25-30)* A flexible tube is well known within the art to provide support and is easily mounted in the wall of a drip chamber. Also, a tube that contains all membranes inside of the tube would be easier to replace or remove for cleaning than many other types of mountings in the event one of the membranes is damaged. It would thus have been obvious to one of ordinary skill to provide a

support structure, such as a tube, to prevent the membrane from collapsing from fluid or gas pressures and allow for replaceable but secure mounting within the drip chamber wall.

n. Regarding claim 14, See citation of Ford in 1.l above. It would have been obvious to one of ordinary skill in the art to make the core of the vent plug of a rigid impervious material so that the vent plug does not collapse due to high pressures within the drip chamber. Alternatively a rigid core of impervious material would be less costly than a plug made entirely of super-absorbent polymer, it would have been obvious to one of ordinary skill in the art to use a rigid core in order to lower the cost of the device.

o. Regarding claim 15, See 1.j regarding the filter/screen as an obstruction to maintain the polymer material within the housing cavity. As for the trapezoidal shape, Ford discloses a generally cylindrical housing cavity. Ford does not disclose expressly a trapezoidal housing cavity. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to give the housing cavity a trapezoidal cross-section because Applicant has not disclosed that a trapezoidal shaped cavity provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with Ford because both cavities will retain the vent plug. Therefore, it would have been an obvious matter of design choice to modify Ford to obtain the invention as specified in claim 15.

p. Regarding claim 16, Ford does not teach a coupling member with a piercing member. However it is notoriously well known within the art that many medical fluid supply bags are accessed via piercing. It therefore would have been obvious to one of ordinary skill in the art to include a piercing member on the coupling member.

q. Regarding claim 17, Ford does not teach a piercing member defining a closable venting conduit and a liquid conduit. However, as in 1.a above. It would have been obvious to one of ordinary skill in the art to define a closable venting conduit and liquid conduit in the coupling member, or in this case a piercing member, in order to remove as much air from the system as possible so as to not cause a gas embolism.

r. Regarding claim 18, Ford teaches, *"Inlet line may also terminate in a nozzle (not shown) that is designed to form the fluid delivered through inlet line 14 into droplets before falling into interior chamber 26." (Col.4 lines 50-52, emphasis added)* A nozzle is most often a type of funnel.

s. Regarding claim 19, See 1.p above and 1.a above for combination of the device of Knighton with Ford. The device of Knighton is capable of preventing air trapped above the membrane from entering the drip chamber once the container is empty.

t. Regarding claim 20, See 1.p above and 1.a above for combination of the device of Knighton with Ford. The device of Knighton is capable of allowing trapped air to escape to the atmosphere.

u. Regarding claim 21, Ford teaches, *"Inlet line may also terminate in a nozzle (not shown) that is designed to form the fluid delivered through inlet line 14 into droplets before falling into interior chamber 26." (Col.4 lines 50-52, emphasis added)*

v. Regarding claim 23, See 1.j above. It would have been obvious to one of ordinary skill in the art to provide a shield for the vent plug to prevent contamination of the system.

w. Regarding claim 24, See 1.a above.

x. Regarding claim 25, See 1.h above.

y. Regarding claim 26, See 1.j above.

z. Regarding claim 27, See 1.j above.

aa. Regarding claim 28, See 1.l above.

bb. Regarding claim 29, See 1.m above.

cc. Regarding claim 30, See 1.n above.

dd. Regarding claim 31, See 1.a above.

ee. Regarding claim 32, See 1.h above

ff. Regarding claim 33, See figure 5 of Alchas and see 1.a above for the combination of Ford and Alchas. When the vent plug of Ford were to be placed on the side of the drip chamber as in Alchas, it would satisfy this claim.

gg. Regarding claim 34, See 1.h above.

hh. Regarding claim 35, See 1.g above.

ii. Regarding claim 36, See 1.h above.

jj. Regarding claim 37, See 1.j above.

kk. Regarding claim 38, See 1.n above.

ll. Regarding claim 39, See 1.j above. It would have been obvious to one of ordinary skill in the art to provide a shield for the vent plug to prevent contamination of the system.

mm. Regarding claim 40, See 1.a above. The first section would be considered the part of the drip chamber that is NOT the vent plug, and the second section would be considered the vent plug.

nn. Regarding claim 41, See 1.h above

oo. Regarding claim 42, See 1.g above.

pp. Regarding claim 43, See 1.a above. The drip chamber 10 of Ford regulates the flow rate of solution from the coupling assembly to the patient conduit. Furthermore, as established previously by Ford, Knighton, and Bormann et al, the vent plug allows air out until wetted which is desirable because any air bubbles that enter a patient will cause a gas embolism. Thus it would have been obvious to one of ordinary skill in the art to include a vent plug in the end cap so that air may escape until it is wetted by the medical fluid being delivered after which it will be sealed so that no air is delivered to the patient to cause a gas embolism.

qq. Regarding claim 44, See 1.a above. The end cap of Knighton is releasably detachable. Therefore it would have been obvious to one of ordinary skill in the art to make the end cap releasably detachable for easier transportation of the

system, easier cleaning and easier replacement if the module becomes damaged.

rr. Regarding claim 45, A luer connection is notoriously well known within the art as a way of reversibly sealing medical devices together.

ss. Regarding claim 46, See 1.h above

tt. Regarding claim 47, See figure 1 of Ford, item 10 is a drip chamber.

uu. Regarding claim 48, It is notoriously well known within the art to use an infusion pump to regulate flow rates of medical fluids to a patient.

vv. Regarding claim 49, See 1.a above. It would have been obvious to one of ordinary skill to keep the patient isolated from the drip chamber via the switch in the device of Knighton (see 1.d above) until the vent plug is wetted so that the drip chamber will properly regulate the flow of medical fluid to the patient.

ww. Regarding claim 50, See 1.oo above.

xx. Regarding claim 51, See figure 1 of Ford, clamp 20.

yy. Regarding claim 52, See a above.

zz. Regarding claim 53, The termination end cap (device of Knighton, see a above for combination with Ford) is capable of allowing the formation of a reservoir in the drip chamber while permitting the escape of air from the conduit via the end cap.

aaa. Regarding claim 54, See 1.zz above.

bbb. Regarding claim 55, See a and 1.zz above.

2. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ford (5,779,674) in view of Alchas (4,952,210), Knighton (4,571,244), Bormann et al (6,336,916) and Meisch (4,465,479).

ccc. Regarding claim 22, See 1.a regarding all but splash guard. While Ford substantially discloses the apparatus as claimed, it does not disclose a plash guard connected to the wall above the vent plug in the interior of the drip chamber and extending across the vent plug. However, Meisch discloses an annular, conical splash guard for a drip chamber to protect the filter vents against gross or excessive splashing. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide air vents for the vent plug as taught by Meisch to the filter of Ford to protect against gross or excessive splashing.

Response to Arguments

3. Applicant's arguments filed 4-11-2008 have been fully considered but they are not persuasive. Applicant argues that the vent of Alchas is intended to allow air to enter the container, the opposite of the claimed invention. However, the vent is capable of allowing air to both enter and leave. Applicant argues that the vent of Ford must be vertical, while that is true, in the office action dated 12-7-2007, it is specifically stated that when combined with the references of Alchas and Bormann et al that a long, hanging vent is unnecessary as the vent in Alchas for example is flat and in the side of the device. Applicant argues that Ford teaches the vent be made of a hydrophobic

material and that no showing is made why to modify Ford. Yet a specific showing is made in 1.a above. The citation from Bormann et al is Col.3 lines 15-22. The filter still allows air in or out as required by Ford, but it takes it one step further by allowing the drip chamber to become sealed once a predetermined level is reached. The same citation is brought to the attention of the Applicant regarding limiting the amount of solution that passes into the drip chamber, which is intended use anyway of which the device is capable of. Applicant also argues that the vent is required to be in the "termination end" of the conduit. A citation is provided in Knighton (Col.1 lines 66-68 to Col.2 lines 1-2) that specifically indicates the vent of Knighton is inserted into an IV line between the device and a patient.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRADLEY J. OSINSKI whose telephone number is (571)270-3640. The examiner can normally be reached on M-Th 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley J Osinski/
Examiner, Art Unit 3767

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771